

REMARKS

Applicant would like to thank Examiner Pellegrino for the personal interview with Applicant's representatives on August 4, 2004.

Claims 1, 11 and 17 have been amended. Claims 18 and 20 have been cancelled, and new claims 22-24 have been added. No new matter has been introduced. Reconsideration is respectfully requested in view of the above amendments and following remarks.

Applicant's Response to 35 U.S.C. § 103 Rejection over Schmitt in view of Kuwahara

Claims 1-6, 8-17 and 19 are rejected under 35 U.S.C. § 103(a), as allegedly being obvious over U.S. Patent No. 5,443,499 to Schmitt (hereinafter "Schmitt") in view of WO 99/04727 to Kuwahara et al., which is translated as U.S. Patent No. 6,346,119 (hereinafter "Kuwahara"). Applicant respectfully traverses the rejection on the basis that the combination of references fails to render the claims obvious, as amended herein.

Schmitt has been cited for its alleged disclosure of a tubular fabric for use as a vascular prosthesis, which has a denier of 115 and 100 filaments that are partially oriented to be used for graft material and can be attached with a stent. ." The Examiner acknowledges that Schmitt does not disclose polymeric filaments of a naphthalene copolymer. According to the Examiner, "Schmitt discloses the plurality of polymeric filaments comprise a combination of drawn and partially drawn radial filaments."

Kuwahara has been cited for its disclosure of a stent-graft with a tubular fabric made of a woven fabric having a plurality of polyester fibers, which may be polyethylene naphthalate (PEN). The Examiner alleges that it would have been obvious to one skilled in the art to use the naphthalene dicarboxylate derived polymeric filaments taught by Kuwahara in the prosthesis taught by Schmitt to thereby arrive at the present invention.

Applicant has amended claims 1, 11 and 17 to further define the invention. In particular, Applicant has added a recitation in claims 1, 11 and 17 that further defines the polymeric filaments of the implantable prosthesis fabric. More specifically, Applicant has amended claims 1 and 17 to recite that the polymeric filaments comprise at least two naphthalene dicarboxylate derivatives. Applicant has amended claim 11 to recite that the polymeric filaments comprise both polyethylene naphthalate and polybutylene naphthalate. Support for these amendments can be found on pages 8 and 31 of the specification as originally filed.

As acknowledged by the Examiner, Schmitt fails to disclose polymeric filaments made of a naphthalene dicarboxylate derivative. Accordingly, Schmitt also fails to disclose, teach or suggest polymeric filaments made of at least two naphthalene dicarboxylate derivatives, as well as the specific combination of polyethylene naphthalate and polybutylene naphthalate, as recited in the amended claims.

Although the Examiner alleges that Kuwahara discloses polyethylene naphthalate filaments, and thereby allegedly renders the previous claims obvious in combination with Schmitt, nowhere in Kuwahara are combinations of at least two naphthalene dicarboxylate derivatives, nor the specific combination of polyethylene naphthalate and polybutylene naphthalate, disclosed, taught, or suggested. Therefore, Kuwahara fails to cure the deficiencies of Schmitt as a reference. In view thereof, amended claims 1, 11 and 17, as well as new claims 22 and 23, are not obvious in view of the teachings of Schmitt in combination with Kuwahara.

Furthermore, Schmitt also fails to disclose, teach or suggest a combination of undrawn and partially drawn radial filaments, as recited in claims 1, 11 and 17, as well as new claim 24. Although the Examiner alleges that Schmitt teaches "a prosthesis with both drawn and partially drawn filaments," Applicant's current claims are not directed to such a combination of filaments. Rather, Applicant's claims recite a combination of undrawn and partially drawn

radial filaments. More specifically, Schmitt teaches prostheses having longitudinally drawn filaments. The radial filaments of Schmitt's prostheses are either undrawn or partially drawn. Nowhere in Schmitt, however, is it taught or suggested to have radial filaments that are a combination of both undrawn and partially drawn filaments. Indeed, such a combination would destroy the intent of Schmitt's invention.

By way of explanation, Schmitt seeks to provide an expandable tubular prosthesis which once implanted allows controlled expansion in a circumferential direction and limits expansion in a longitudinal direction. The Schmitt prostheses are designed to be implanted and radially enlarged to match the natural vessel to which it is attached. For example, if the physician implants a prosthesis which is too small to match the radial dimension of the natural vessel, it can be expanded by placing a balloon catheter or other similar device, within the lumen of the prosthesis and dilation, *in vivo*, can be performed such that the radial dimension of the prosthesis now matches that of the natural vessel. Other applications include the use in children, whereby as the child grows, the prosthesis can be circumferentially expanded, *in vivo*, to match the child's natural vessel. In this manner, once implanted, Schmitt's prosthesis need not be replaced using traditional surgical replacements. In order for Schmitt to carry out his invention properly, the radial yarns must be capable of being further stretched once they are implanted. This stretching must occur in a controlled manner to provide uniform radial expansion in the body. Accordingly, at column 6, lines 44-51, Schmitt states the following:

In the manufacture of the prosthesis of the present invention, both drawn yarns as well as undrawn yarns or partially drawn yarns are employed. The undrawn or partially drawn yarns are incorporated into the chosen textile pattern in the direction upon which drawing will result in a larger diameter of the device.

Schmitt's combinations of different yarns are shown in columns 4 and 6. In column 4, Schmitt states that yarns which are used in the circumferential direction (radial direction) "have

not been drawn or only partially drawn, allowing for future radial expansion through *vivo* drawing, i.e., stretching, beyond the yield point, at which time the tubular prosthesis remains fixed at the increased diameter. Schmitt, however, never allows for the combination of undrawn and partially drawn yarns in the radial direction. Only the alternative of one or the other is possible in Schmitt because to do otherwise would be contrary to his teachings, as it is necessary to control the in vivo stretching such that the prosthesis uniformly expands radially in the body. A combination of undrawn and partially drawn radial yarns would not uniformly radially expand in the body.

Therefore, Schmitt fails to disclose, teach or suggest a combination of undrawn and partially drawn radial filaments. Kuwahara also fails to teach such a combination of polymeric filaments, and therefore, cannot cure the deficiencies of Schmitt.

In view of the above, amended claims 1, 11 and 17, and thus any claims that depend therefrom, as well as new claims 22-24, are not obvious in view of the teachings of Schmitt in combination with Kuwahara. Applicant respectfully requests reconsideration and withdrawal of the Section 103 rejection based on this combination.

Applicant's Response to 35 U.S.C. § 103 Rejection over Schmitt in view of Kuwahara and Vanney

Claims 18 and 20 are rejected under 35 U.S.C. § 103(a), as allegedly being obvious over Schmitt in view of Kuwahara and U.S. Patent No. 5,876,436 to Vanney et al. (hereinafter "Vanney"). Applicant has cancelled claims 18 and 20 herein, and therefore submits that the rejection has been overcome.

Applicant's Response to 35 U.S.C. § 103 Rejection over Schmitt in view of Kuwahara and Schmitt '970

Claim 21 is rejected under 35 U.S.C. § 103(a), as allegedly being obvious over Schmitt in view of Kuwahara and U.S. Patent No. 5,697,970 to Schmitt (hereinafter "Schmitt '970"). Applicant respectfully traverses the rejection on the basis that the Examiner has failed to establish a prima facie case of obviousness.

The Examiner admits that Schmitt and Kuwahara fail to disclose a prosthesis having a series of crimps. The Examiner alleges, however, that Schmitt '970 teaches that crimps may be applied to a graft prosthesis. According to the Examiner, it would have been obvious to one skilled in the art to incorporate naphthalene dicarboxylate derived polymeric filaments as disclosed in Kuwahara and use crimps as taught by Schmitt '970 with the prosthesis of Schmitt.

As discussed in detail above, Schmitt fails to disclose, teach or suggest a combination of undrawn and partially drawn radial filaments, which recitation also is required by claim 21. Also discussed above, Kuwahara fails to cure the deficiencies of Schmitt in this regard. Further, Schmitt '970 is merely cited for its teaching of crimping prostheses, and similarly fails to disclose, teach or suggest prostheses having a combination of undrawn and partially drawn radial filaments. Thus, Schmitt '970 also fails to cure the deficiencies of Schmitt as a reference. In view thereof, Applicant respectfully submits that the cited combination of art fails to render claim 21 obvious.

Moreover, Kuwahara actually teaches away from crimping its graft tubes, stating that "[i]t is preferable that the tubes are not subjected to a crimp processing." Kuwahara, Col. 5, lines 3-4; *see Tec Air, Inc. v. Denso Mfg. Michigan, Inc.*, 52 USPQ2d 1294, 1298 (Fed. Cir. 1999), *citing In re Gurley*, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994) ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction

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divergent from the path that was taken by the applicant or if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant.""). In view of such statement, any reference showing crimping would not be properly combinable with Kuwahara. Schmitt '970 and Kuwahara have divergent and contrary teachings with respect to crimping and as such, Schmitt '970 is not properly combinable with Kuwahara.

Therefore, claim 21 is not obvious in view of the teachings of Schmitt in combination with Kuwahara and Schmitt '970. Applicant respectfully requests reconsideration and withdrawal of the Section 103 rejection based on this combination.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

Respectfully submitted,



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